



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Environmental Health
250 Washington St., 7th Floor, Boston, MA 02108-4619
Phone: 617-624-5757 Fax: 617-624-5777
TTY: 617-624-5286

DEVAL L. PATRICK
GOVERNOR

TIMOTHY P. MURRAY
LIEUTENANT GOVERNOR

JUDYANN BIGBY, M.D.
SECRETARY

JOHN AUERBACH
COMMISSIONER

MEMORANDUM

TO: Commissioner John Auerbach and Members of the Public Health Council

FROM: Suzanne K. Condon, Director
Bureau of Environmental Health

RE: Request for Promulgation of Amendments to Ban Leaded Toy Jewelry under
105 CMR 650.000; Hazardous Substance Regulations

DATE: March 12, 2008

INTRODUCTION

The purpose of this memo is to request the Council's approval of amendments to 105 CMR 650.000, Hazardous Substances Regulations. The proposed amendments will protect children's health by instituting a ban on the manufacture, transport, or sale of children's jewelry containing a dangerous level of lead.

BACKGROUND

The Massachusetts Lead Law (MGL c.111, §§ 189A -199B) bans toys, eating or drinking utensils with a coating of paint, enamel or glaze with a lead content of 600 ppm or greater, but the ban does not apply to lead in metallic form. Thus the MDPH is proposing this regulation under the Hazardous Substance Act (MGL c.94B) due to the presence of lead found in the metallic composition of samples of children's jewelry collected during the past three years from vending machines, children's toy sections of retail stores, displays in areas near the front entrance of a store, and jewelry counters in stores across the Commonwealth. Although the percent of children's jewelry samples containing lead has decreased from that found in samples collected in 2004, more than one in ten samples collected in 2007 had sufficiently high lead levels that present serious health concerns to young children. In all cases, these items present the most serious health concerns if the jewelry item is swallowed, but importantly, some of the items can also present significant health concerns if mouthed by young children, a far more common behavior than swallowing. Thus, despite numerous voluntary recalls of these products issued by the U.S. Consumer Product Safety Commission (CPSC) over the past few years, children's jewelry sold in Massachusetts continues to be found to contain dangerous levels of lead.

The proposed amendments were presented to the Council on September 12, 2007. The Council expressed strong support for the proposed amendments and asked that MDPH consider possibly expanding the scope of the regulations to other children's products and adding language to the regulations relative to documentation of compliance with the proposed regulations. As a result of these recommendations, MDPH added language relative to such documentation to the proposed regulations and solicited public comment on the following question: Are there other leaded children's products that the Department should consider banning?

Public hearings were held in Framingham on November 15 and in Boston on November 16, 2007. Written testimony was accepted until Friday, November 23, 2007.

PUBLIC COMMENTS AND THE DEPARTMENT'S RESPONSE

A total of 34 individuals submitted comments to MDPH/BEH. Attached to this memo is a detailed summary of the comments and MDPH's responses to the comments.

Definition of Children

Most commenters asked that "children" be specifically defined (the proposed regulation had no definition). The vast majority of comments suggested a definition of less than 12 years of age, based on a recommendation made by the American Academy of Pediatrics (testimony of which was submitted to MDPH). Representatives of the jewelry industry urged a definition of less than 7 years old, based on the definition adopted by a California law. MDPH is recommending that the age definition be children under 14 years of age. The industry's stated position is that it does not now market to children under age 6 but there are documented cases of lead poisoning in this age group, presumably from access to their older siblings' jewelry. If the age limit were set at 12 years, packaging could state "for teenagers," and hence be exempt, making the product potentially accessible to young children emulating their older siblings.

Total Lead Content and Leachable Lead Thresholds

The thresholds of less than 600 ppm total lead and 15 µg/d accessible lead, as originally proposed, will be the dual thresholds. Many comments suggested that a level of 40 ppm be established as the threshold for total lead. MDPH staff analysis of CPSC data demonstrates that jewelry with less than 40 ppm can still expose a child to dangerous levels of lead. In 31 percent of the cases where a jewelry item had a total lead content of 40 ppm or less, the item failed the companion test of 15 µg/d accessible lead. Thus a single total lead content threshold does not ensure public health protection. We believe the dual standards proposed are more health-protective than a standard based solely on total lead content. The accessibility standard reflects the actual amount of lead the child can absorb into the blood, and it is critical that children's jewelry meet this standard in order to adequately protect children from dangerous lead levels.

Industry representatives have generally endorsed adopting the California law, which stipulates different total lead content limits depending on the type of jewelry item. The California law does not have an accessibility based standard, as we are proposing, and the industry has stated that the accessibility standard of 15 µg/d is too low and would impose serious economic impacts on the industry. However, despite raising this issue in various forums (e.g., telephone, in-person meetings), the industry did not supply any specifics on the economic impact. We understand that

we are proposing the most stringent standards in the country and it is our hope that others states will follow suit (we have been in discussion with several other states, who have asked for our technical support documents).

Toy Jewelry

The industry commented that “toy jewelry” was jewelry that was made for a child to dress a doll or something very small (Fashion Jewelry Trade Association). Thus, to clarify that the proposed regulations are not restricted to such jewelry, we have replaced the word “toy” with “children’s” in describing “children’s leaded jewelry.”

Expanding Scope of Products Covered Under this Proposed Amendment

The overwhelming majority of comments received supported expanding the ban to include other children’s products containing lead and setting a limit of total lead content in all of these products, including children’s jewelry, of 40 parts per million (40 ppm). Comments echoed recommendations of the American Academy of Pediatrics.

Due to the demonstrated health hazard that exists related to the mouthing and swallowing of jewelry items, we believe it is in the best interests of public health to move forward with the lead in jewelry regulations while concurrently evaluating other children’s products containing lead.

MDPH will carefully consider comments received in support of a broader ban and will consider all available data on children’s products, including those by the CPSC, advocacy groups, or others. To enhance these efforts, MDPH will be convening a public health discussion group to ensure that all relevant data are considered. Products that are found to present an unacceptable risk to children based on accessibility will be identified. Following that, MDPH will return to the Council with proposed regulations to further regulate lead in children’s products.

Laboratory Methods and Guidance Document

MDPH did not receive specific formal comments on the laboratory methods contained in the proposed regulations. However, subsequent research has revealed that more than one laboratory method may be appropriate for either or both of the total lead content or accessible lead determinations. Hence, in order to be as flexible as possible, MDPH is proposing to add to the language on the specified methods the following: “...or similar methods subject to approval by the Department.” BEH is developing a guidance document that will contain details relating to the implementation and enforcement of the regulations. Details will include acceptable laboratory methods, certification programs, and other relevant information. Other details in the guidance document will include required documentation for retailers, distributors, and manufacturers to demonstrate compliance with the regulations.

Because MDPH believes the industry reasonably needs time to come into compliance, we are proposing that the regulations not go into effect until June 13, 2008, when we will publish the final regulations in the Massachusetts Register. We will also provide the industry and other interested parties the opportunity for a 30-day comment period, starting on March 12, 2008, on the draft guidance document discussed above.

CONCLUSIONS

We are requesting approval for promulgation of the amendments. Following PHC approval, the Department will file the amendments with the Secretary of the Commonwealth for publication in the Massachusetts Register on June 13, 2008, as discussed above.